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10/613,675	07/03/2003	John H. Erickson	64862/PO63US/10503216	7289

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EXAMINER

SMITH, TERRI L

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/613,675

Applicant(s)

ERICKSON, JOHN H.

Examiner

Terri L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 1-28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12-16-03</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

1. Figure 1, as described on page 8 in line 3 of the specification, should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office Action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the Examiner, the Applicant will be notified and informed of any required corrective action in the next Office Action. The objection to the drawings will not be held in abeyance.

### ***Specification***

2. The disclosure is objected to because of the following informalities: On page 13, it appears that in line 29, the first occurrence of the word "the" should be a different word, perhaps "then," because the sentence is not clear as written.

On page 14, the sentence beginning in line 3, "The specific composition ... meet the desired]," is an incomplete sentence.

Appropriate correction is required.

### ***Claim Objections***

3. Claims 10, 17, and 23 are objected to because of the following informalities: In claim 10 on lines 7–8, the word "and" appears back to back making the claim unclear.

Similarly, in claim 17 on lines 8–9, the word "and" appears back to back making the claim unclear.

In claim 23, there appears to be a typographical error wherein the letter “o” should probably be the word “to.”

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1–4, 7–19 and 22–25 are rejected under 35 U.S.C. 102(b) as being anticipated by Flynn et al., U.S. Patent 6,141,594.

With respect to claims 1, 7, 10, and 17, Flynn et al. disclose a lead system (100, 200), a first lead body having at least one electrode/(first lead) (Figs. 1A–1B, elements 130/152); a second lead body having at least one electrode/(second lead) (Figs. 1A–1B, elements 132/154); a connection member coupled to a first lead body and a second lead body and operable when a connecting member (141) is in a first state to maintain at least a portion of a first lead body in a first position relative to at least a portion of a second lead body/(means coupled to a first lead and a second lead for maintaining at least a portion of a first lead in a first portion of a second lead) (Figs. 1A–1B); a connection member (Figs. 4A–4B, element 166), comprising, a first portion attached to a first lead, a second portion attached to a second lead and coupled to a first portion, a third portion coupled to a first portion and a second portion, and wherein at least one of a first

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portion and a second portion/(and a third portion) comprises resorbable material (Figs. 4A–4B, column 6, lines 49–53 and 59–63; column 10, lines 27–29).

Regarding claims 2, 4, 8, 12, and 15, Flynn et al. disclose at least a portion/(a third portion) of a connection member/(means for maintaining) comprises resorbable material (column 6, lines 49–53 and 59–63; column 10, lines 27–29).

With respect to claim 3, Flynn et al. disclose a first state relates to a lead after insertion into a human body (Fig. 9).

Regarding claim 9, Flynn et al. disclose means for placing at least a portion of a first lead in a second position relative to at least a portion of a second lead (Figs. 1A–1B and 9).

With respect to claim 11, Flynn et al. disclose a first portion and a second portion are coupled using a third portion (Figs. 4A–4B, element 166) [Examiner notes that this continuous dissolvable mannitol medical adhesive is consistent with Applicant's disclosure that the portions 104, 106, 108 may also be made into one unitary portion, and the dissection into three portions is for illustrative purposes only (page 12, lines 14–20)].

Regarding claim 13, Flynn et al. disclose a connection member orients a first lead with respect to a second lead (Figs. 4A–4B).

With respect to claim 14, Flynn et al. disclose a connection member is operable to maintain a predetermined maximum distance between a first lead and a second lead prior to when at least one of a first portion and a third portion comprising resorbable material resorbs in a body (Figs. 4A–4B).

Regarding claim 16, Flynn et al. disclose a connection member couples a first lead to a second lead in a first fixed relation prior to insertion of a lead into a body (Figs. 4A–4B) and in a second fixed relation after insertion of a lead into a body (Fig. 9).

With respect to claims 18–19, Flynn et al. disclose a lead system (Figs. 1A–1B, element 100), comprising: a first lead body (130/152), comprising, a proximal end (102) and a distal end (104), at least one contact electrode positioned proximate a proximal end (134, terminal pin), at least one electrode positioned proximate a distal end (110, first electrode assembly), and at least one conductor extending through a lead body and electrically connecting a contact electrode and an electrode (column 5, lines 15–18; Figs. 2–3B); a second lead body (132/154), comprising, a proximal end (102) and a distal end (104), at least one contact electrode positioned proximate a proximal end (136, terminal pin), at least one electrode positioned proximate a distal end (112, second electrode assembly), and at least one conductor extending through a lead body and electrically connecting a contact electrode and an electrode (column 5, lines 15–18; Figs. 2–3B); and a connection member (Figs. 4A–4B), comprising, a first portion attached to a distal end of a first lead body, a second portion attached to a distal end of a second lead body, and a third portion coupled to a first portion and a second portion (Figs. 4A–4B), and at least one of a first portion, a second portion, and a third portion comprises resorbable material (column 6, lines 49–53 and 59–63); a member is operable to maintain a first lead body and a second lead body in a substantially fixed position with respect to each other (Figs. 4A–4B).

With respect to claims 22–23, Flynn et al. disclose providing a first lead body (130/152) having a distal end (104); providing a second lead body (132/154) having a distal end (104); coupling a distal end of a first lead body to a distal end of a second lead body with a connection

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member (Figs. 4A–4B; element 166), at least a portion of a connection member comprising resorbable material (column 6, lines 49–53 and 59–63); a connection member comprises a first portion, a second portion, and a third portion, a first portion coupled to a second portion and a second portion coupled to a third portion (Figs. 4A–4B; element 166), and further comprising: coupling a first portion to a distal end of a first lead body; and coupling a third portion of a distal end of a second lead body (Figs. 4A–4B; element 166).

Regarding claims 24–25, Flynn et al. disclose system (Fig. 9) for stimulating a portion of a body, a system comprising: a source for generating a stimulus (Fig. 9); and an implantable lead (Figs. 1A–1B) for receiving a stimulus from a source (Fig. 9), an implantable lead comprising, a first lead (130/152); a second lead (132/154); and a connection member (Figs. 4A–4B; element 166), comprising, a first portion attached to a first lead, a second portion attached to a second lead, and a third portion coupled to a first portion and a second portion (Figs. 4A–4B; element 166), and wherein at least one of a first portion, a second portion, and a third portion comprises resorbable material (column 6, lines 49–53 and 59–63); a position of a first lead is substantially fixed with respect to a position of a second lead after a lead is inserted within a body (Figs. 4A–4B).

6. Claims 1, 3, and 5–7 are rejected under 35 U.S.C. 102(e) as being anticipated by Cross, Jr. et al., U.S. Patent 6,587,733.

With respect to claims 1, 3, and 5–6, Cross, Jr. et al. disclose a lead (Fig. 1), comprising: a first lead body (12) having at least one electrode (16); a second lead body (14) having at least one electrode (16) (Fig. 2); and a connection member (20, urethane bridge) coupled to a first lead

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body and a second lead body and operable when a connecting member is in a first state to maintain at least a portion of a first lead body in a first position relative to at least a portion of a second lead body (Fig. 2) (claim 1); a first state relates to a lead after insertion into a human body (Fig. 2) (claim 3); a connection member is further operable when a connecting member is in a second state to maintain a first lead body in a second position relative to a second lead body (Fig. 3) (claim 5); a second state relates to a lead after insertion into a human body (Fig. 3) (claim 6).

Regarding claim 7, Cross, Jr. et al. disclose lead system (10), comprising: a first lead (12); a second lead (14); and means coupled to a first lead and a second lead for maintaining at least a portion of a first lead in a first position relative to at least a portion of a second lead (20).

7. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al., U.S. Patent 5,997,569.

Chen et al. disclose inserting a distal end of a lead into a human body (column 5, lines 66–column 6, line 1; Figs. 3–6), a lead comprising, a first lead body (40), a second lead body (40), and a connection member (44, circular link); after inserting a lead into a human body, disengaging a connection member to allow a connection member to maintain a first lead body and a second lead body in a first position with respect to each other (Fig. 3).

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 2, 4, and 8–17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cross, Jr. et al. and in view of Flynn et al., U.S. Patent 6,141,594.

Regarding claims 2, 4, 8, 12, and 15, Cross, Jr. et al. disclose the essential features of the claimed invention except for at least a portion (a third portion) of a connection member/means for maintaining comprises resorbable material. However, Flynn et al. disclose at least a portion (a third portion) of a connection member/means for maintaining comprises resorbable material (column 6, lines 49–53 and 59–63; column 10, lines 27–29) to aid in the installation of the lead within a patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Cross, Jr. et al. to include at least a portion of a connection member comprises resorbable material, as taught by Flynn et al. to aid in the installation of the lead within a patient.

With respect to claims 9 and 13, Cross Jr. et al. disclose means for placing at least a portion of a first lead in a second position relative to at least a portion of a second lead (Fig. 3) (claim 9) and a connection member orients a first lead with respect to a second lead (Fig. 2) (claim 13).

Regarding claim 10, Cross Jr. et al. disclose a lead system (10), comprising: a first lead (12); a second lead (14); and a connection member (20), comprising, a first portion attached to a first lead (Fig. 2), a second portion attached to a second lead (Fig. 2) and coupled to a first portion (Fig. 6), but Cross, Jr. et al. do not disclose at least one of a first portion and a second

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portion comprises resorbable material. However, Flynn et al. disclose at least one of a first portion and a second portion comprises resorbable material (column 6, lines 49–53 and 59–63; column 10, lines 27–29) to aid in the installation of the lead within a patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Cross, Jr. et al. to include at least a portion of a connection member comprises resorbable material, as taught by Flynn et al. to aid in the installation of the lead within a patient.

With respect to claim 11, Cross Jr. et al. disclose a first portion and a second portion are coupled using a third portion (column 4, lines 6–8) [Examiner notes that this continuous urethane bridge is consistent with Applicant's disclosure that the portions 104, 106, 108 may also be made into one unitary portion, and the dissection into three portions is for illustrative purposes only (page 12, lines 14–20)].

Regarding claim 14, Cross, Jr. et al. do not disclose a connection member is operable to maintain a predetermined maximum distance between a first lead and a second lead prior to when at least one of a first portion and a third portion comprising resorbable material resorbs in a body. However, Flynn et al. disclose a connection member is operable to maintain a predetermined maximum distance between a first lead and a second lead prior to when at least one of a first portion and a third portion comprising resorbable material resorbs in a body (Figs. 4A–4B) to aid in the installation of the lead within a patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Cross, Jr. et al. to include at least a portion of a

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connection member comprises resorbable material, as taught by Flynn et al. to aid in the installation of the lead within a patient.

With respect to claim 16, Cross, Jr. et al. disclose a connection member couples a first lead to a second lead in a first fixed relation prior to insertion of a lead into a body (Fig. 2) and in a second fixed relation after insertion of a lead into a body (Fig. 2). [In the broadest reasonable interpretation, Examiner is interpreting the first and second fixed relation as the same because the claim does not explicitly state that the first and second fixed relation are the same or different.]

Regarding claim 17, Cross, Jr. et al. disclose a lead system (10), comprising: a first lead (12); a second lead (14); and a connection member (20), comprising, a first portion attached to a first lead, a second portion attached to a second lead, and a third portion coupled to a first portion and a second portion (column 4, lines 1–8), but Cross, Jr. et al. do not disclose at least one of a first portion, a second portion and a third portion comprises resorbable material. However, Flynn et al. disclose at least one of a first portion, a second portion and a third portion comprises resorbable material (column 6, lines 49–53 and 59–63; column 10, lines 27–29) to aid in the installation of the lead within a patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Cross, Jr. et al. to include at least a portion of a connection member comprises resorbable material, as taught by Flynn et al. to aid in the installation of the lead within a patient.

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10. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al., U.S. Patent 5,997,569.

Chen et al. disclose the essential features of the claimed invention except for at least a portion of a connection member comprises resorbable material, and after a period of time, a portion of a connection member comprising resorbable material resorbs into a human body. It would have been an obvious matter of design choice to one of ordinary skill in the art to modify the material of a connection member as taught by Chen et al. by using resorbable material that resorbs into a human body after a period of time because it is well known in the art to use time dependent resorbable material to temporarily coat or secure portions of implantable devices for ease of implantation of a device or extraction of a device at a later time and to allow implantation of the device to be completed to realize maximum effective operation of the device.

11. Claims 26–28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flynn et al. as applied to claim 24 above, and in view of Cooke et al., U.S. Patent 5,643,328.

Flynn et al. disclose the essential features of the claimed invention except for a source comprises a wireless receiver and an implantable pulse generator, and a controller operable for communicating with a source and controlling a source. However, Cooke et al. disclose a source comprises a wireless receiver (Fig. 3; column 4, lines 47–51) and an implantable pulse generator (Fig. 1), and a controller operable for communicating with a source and controlling a source (Fig. 3) to provide for an effective implantable cardiac stimulation system with a reliable patient communication apparatus.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Flynn et al. to include a source comprises a wireless receiver and an implantable pulse generator, and a controller operable for communicating with a source and controlling a source, as taught by Cooke et al. to provide for an effective implantable cardiac stimulation system with a reliable patient communication apparatus.

*Conclusion*

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



TLS

April 12, 2006

12 April 2006



GEORGE R. EVANISKO  
PRIMARY EXAMINER  
4/12/6